

09/931,736

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EXAMINER DAVIS, DEBORAH A PAPER NUMBER ART UNIT

1641 DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
		09/931,736	SHAO, WEIPING
	Office Action Summary	Examiner	Art Unit
	•	Deborah A Davis	1641
	The MAILING DATE of this communicati		
Period 1	or Reply		•
THE - Ext afte - If th - If N - Fai - Any	HORTENED STATUTORY PERIOD FOR I MAILING DATE OF THIS COMMUNICAT ensions of time may be available under the provisions of 37 or SIX (6) MONTHS from the mailing date of this communicate period for reply specified above is less than thirty (30) day (10) period for reply is specified above, the maximum statutory lure to reply within the set or extended period for reply will, by reply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b).	TION. CFR 1.136(a). In no event, however, may a rejtion. s, a reply within the statutory minimum of thirty / period will apply and will expire SIX (6) MONT by statute, cause the application to become ABA	ply be timely filed (30) days will be considered timely. HS from the mailing date of this communication. NDONED (35 U.S.C. § 133).
1)区	Responsive to communication(s) filed of	on <u>16 May 2003</u> .	
2a) <u></u>	This action is FINAL . 2b)	This action is non-final.	
3) Disposi	Since this application is in condition for closed in accordance with the practice tion of Claims	allowance except for formal matt under <i>Ex parte Quayle</i> , 1935 C.D	ters, prosecution as to the merits is 0. 11, 453 O.G. 213.
-	Claim(s) <u>1-75</u> is/are pending in the appl	ication.	
,	4a) Of the above claim(s) <u>19-75</u> is/are wi		·
5)[Claim(s) is/are allowed.		
6)⊠	Claim(s) <u>1-18</u> is/are rejected.		
7)[Claim(s) is/are objected to.		
8)[Claim(s) are subject to restriction	and/or election requirement.	
Applica	tion Papers		
	The specification is objected to by the Ex		
10)	The drawing(s) filed on is/are: a)		
	Applicant may not request that any objection		
11)	The proposed drawing correction filed on		sapproved by the Examiner.
	If approved, corrected drawings are require	•	
12)	The oath or declaration is objected to by	the Examiner.	
Priority	under 35 U.S.C. §§ 119 and 120		
13)[Acknowledgment is made of a claim for	foreign priority under 35 U.S.C. §	3 119(a)-(d) or (f).
·	a) ☐ All b) ☐ Some * c) ☐ None of:		
	1. Certified copies of the priority doc	uments have been received.	
	2. Certified copies of the priority doc	uments have been received in Ap	oplication No
	3. Copies of the certified copies of the application from the Internation See the attached detailed Office action for	nal Bureau (PCT Rule 17.2(a)).	
14)	Acknowledgment is made of a claim for d	omestic priority under 35 U.S.C.	§ 119(e) (to a provisional application).
15)[_	a) The translation of the foreign langual Acknowledgment is made of a claim for d		
Attachme	, -		
2) 🔲 No	tice of References Cited (PTO-892) tice of Draftsperson's Patent Drawing Review (PTO-	948) 5) Notice of Ir	Summary (PTO-413) Paper No(s) nformal Patent Application (PTO-152)

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-18, in Paper No. 6 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 2-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claims 2-8 recite "an antibody" is indefinite because it is unclear if applicant if referring to the same antibody as in claim 1 or a different antibody. If this is the same antibody, said limitation should recite "said antibody" or "the antibody". Please correct.

6. Claims 14 and 16 recite "tether" in line 2 is indefinite because it unclear as to what this term means. Further, this term is not defined in the specification in such a way that one skilled in the art would understand. Please clarify.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 1-4, 8-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorval et al (USP#5,561,045).

Dorval et al teaches a blocked immunoglobulin that has an antibody portion and a Protein A portion, which are used to detect a plurality of analytes (col. 5, lines 47-50). Protein A is bound to the Fc region of an immunoglobulin of a class that specifically binds to a predetermined analyte (col. 4, lines 28-40). Protein A may be immobilized on a support to be used in a test assay to capture binding partners of either the immunoglobulin or Protein A (col. 9, lines 1-12). Both immunoglobulin and the protein will be bound to a support by hydrophobic coupling, but will be free of interaction between them, such as hydrophobic coupling. The antibody portion of the

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immunoglobulin has at least one antigenic reactive site because both immnoglobulin and the Protein A portion will be free to interact specifically with analytes in a sample (col. 5, lines 31-40). The preferred supports are plates, polymeric beads, porous membranes (col. 6, lines 35-47). The binding of antibodies to molecular species typically involve the highly specific interaction of the variable portion of the antibody wherein this interaction is responsible for specific recognition by antibodies of foreign substances (col. 5, lines 31-36).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 10. Claims 1, 8-10 rejected under 35 U.S.C. 102(b) as being anticipated by Sano et al (USP#665,539).

Sano et al teaches a blocked immunoglobulin that wherein streptavidin-protein A binds to an antibody portion of its immunoglobulin G-binding domain (col. 1, lines 61-65). The antibody portion of the immunoglobulin contains an antigen-reactive fragment that is able to form an antigen-antibody complex that can comprise of DNA, RNA, fragment, analogue or a derivative (col. 3, lines 1-4). Streptavidin-Protein A comprises at least one protein A compound wherein it binds to biotin (col 4, lines 32-37). Streptavidin-Protein A can be a fragment because Sano et al discloses that any material

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which is able to specifically recognized or which possesses both antibody-binding domains and also the biotin-binding domains are suitable for use with this present invention (col. 4, lines 22-31).

Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 12. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al and Dorval et al in view of Cabilly et al (USP#4,816,567).

The teachings of Dorval et al and Sano et al are set forth above, but are silent with respect to the number of light and heavy chain variable regions of the antibody.

However, Cabilly et al teaches altered and native immunoglobulins that include constant-variable regions that are immunologically capable of binding predetermined antigens (see summary). Cabilly et al teaches that one pair of heavy and light chain is homologous to antibodies raised against one antigen, while other pairs of heavy and light chain is homologous to those raised against another antigen. This results in the ability to bind two antigens simultaneously. The variable region has the advantage the ease of preparation and has good specificity (col. 6, lines 35-68) and their pairs of heavy and light chains can simultaneously react with more than one antigen (col. 15, lines 45-50).

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It would have been obvious to one of ordinary skill in the art to modify the teachings of Dorval et al and Sano et al to include altered immunoglobulin antibodies as taught by Cabilly et al that contain variable regions of heavy and light chains because they have high sensitivity and are capable of being reactive to more than one antigen simultaneously. Another advantage is that they are easy to prepare (col. 6, lines 65-66).

Conclusion

- 13. No claims are allowed.
- 14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:
- A. James S. Huston (USP#5,476,786) teaches a family of synthetic proteins having affinity for preselected antigens. These proteins comprise of amino acid sequences that have variable heavy and light chains.
- B. Kenten et al (USP#6,087,476) teaches luminescent chimeric proteins which include light or heavy chain immunoglobulin with protein A.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

Deborah A. Davis

CM1, 7D16

June 18, 2003

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600